

No.: 0154.310US--. On page 1, line 2, please delete "0154.003".

Election/Restriction.

Restriction Requirement

Claims 1-35, 37-42, 44-68, and 70-78 are presently pending. Claims 36, 43, and 69 were previously canceled without prejudice to subsequent renewal.

In the Office Action, the Examiner restricted the claims under 35 U.S.C. § 121, requiring Applicants to elect one of the following claim groups for prosecution in the present application:

- I. Claims 1-27, 32, and 77, drawn to a method of producing an antigen presenting cell (APC) including a dendritic cell (DC), classified in Class 435, subclass 377.
- II. Claims 1-27, 32, and 77, drawn to a method of producing an activated APC including an activated DC, classified in Class 435, subclass 375.
- III. Claims 1-2, 21, 23-24, and 30-31, drawn to a method of producing a recombinant transfected APC, classified in Class 435, subclasses 377 and 455.
- IV. Claims 33-35, 37-41, 52-59, 68, and 70-76, drawn to an APC including a DC, and a vaccine, classified in Class 424, subclasses 278.1 and 93.71 and Class 435, subclasses 325 and 372.
- V. Claims 42, 44-45, and 60, drawn to a method of inducing an immune response, classified in Class 424, subclasses 278.1 and 93.71.
- VI. Claims 46-50, drawn to a method of inducing the differentiation of T cells, classified in Class 435, subclasses 347 and 377.
- VII. Claim 51, drawn to T cells, classified in Class 435, subclasses 325 and 372.3.
- VIII. Claims 61-67 and 78, drawn to an ex vivo method of inducing an immune response, classified in Class 424, subclasses 278.1 and 93.71, and Class 435, subclass 377.

Office Action, at 2.

This restriction requirement is respectfully traversed on at least three grounds. First, this requirement restricts subject matter *within* claims, in effect, requiring that single claims (e.g., claim 1) be divided up and presented in several applications (*see, e.g.*, Claim Groups I, II, III). This flatly contravenes accepted law. As stated by the CCPA:

As a general proposition, an applicant has a right to have *each claim* examined on the merits.

* * *

If, however, a single claim is required to be divided up and presented in several applications, that claim would never be considered on its merits. The totality of the resulting fragmentary claims would not necessarily be the equivalent of the original claim. Further, since the subgenera would be defined by the examiner rather than by the applicant, it is not inconceivable that a number of the fragments would not be described in the specification.

* * *

It is apparent that §121 provides the Commissioner with the authority to promulgate rules designed to *restrict an application* to one of several claimed inventions . . . It does not, however, provide a basis for an examiner acting under the authority of the Commissioner to *reject* a particular *claim* on that same basis.

* * *

We hold that a rejection under §121 violates the basic right of the applicant to claim his invention as he chooses.

In re Weber, Soder and Boksay, 198 USPQ 328, 331-332 (CCPA 1978) (emphasis in original and emphasis added) [hereinafter referred to as "*In re Weber*"]. *See also In re Haas*, 179 USPQ 623, 624-625 (CCPA 1973) (hereinafter referred to as *In re Haas I*); *In re Haas*, 198 USPQ 328, 334-337 (CCPA 1978) (hereinafter referred to as *In re Haas II*). Thus, the CCPA ruled that the statute authorizing restriction practice, *i.e.*, 35 U.S.C. § 121, provides no legal authority to impose a restriction requirement on a single claim, even if the claim presents multiple independently patentable inventions. *See In re Weber, In re Haas I*, and *In re Haas II*. Indeed, the CCPA unequivocally stated that there is no statutory basis for rejecting a claim for misjoinder, despite previous attempts by the Patent Office to fashion such a rejection. As noted in *In re Weber*:

So the discretionary power to limit one applicant to one invention is no excuse at all for refusing to examine a broad generic claim--no matter how broad, which means no matter how many independently patentable inventions may fall within it.

In re Weber, 198 USPQ at 334.

As the case law clearly demonstrates, restriction within a single claim is legally improper. An inventor has clear constitutional and statutory rights to claim an invention as it is contemplated, provided the dictates of 35 U.S.C. § 112 are satisfied. *See, e.g.*, MPEP § 803.02; *In re Wolfrum* 179 USPQ 620 (CCPA 1973); *In re Kuehl* 177 U.S.P.Q. 250 (CCPA 1973).

The present restriction requirement is wholly improper, since it restricts within a number of single claims. For example, the following single claims are restricted among two or more of Claim Groups I, II, and III: claims 1-27, 32, and 77. The present restriction requirement precludes Applicants from pursuing the original form of these claims and would force Applicants to file multiple divisional applications that may not capture the intended scope of the invention. Even if Applicants were to file multiple divisional applications to obtain coverage for the claims in each group set forth in the restriction requirement, Applicants would not have the opportunity to have their broader claims examined. In effect, the restriction requirement is reading into Applicants' independent claims limitations that are not present in the claims as filed. If the instant restriction requirement is allowed to stand, Applicants will never be accorded "the basic right of the applicant to claim his invention as he chooses." *In re Weber*, 198 USPQ at 331.

Moreover, regarding Claim Group II, which Examiner states is drawn to a method of producing an *activated APC including an activated DC*, Applicants respectfully point out that no such limitation is present in independent claim 1 (or claims 2-27, 32 and 77 dependent thereon, which are included in Claim Group I), and thus it would be improper to read such limitation into the claim during examination.

Applicants note that the CCPA has explicitly held that review of the improper restriction of a single claim is within the jurisdiction of the Board of Patent Appeals and Interferences and the federal courts. This is in contrast to the review of ordinary restriction requirements, which are not generally subject to appellate review. *See In re Haas I, supra*. Because restriction of a single claim into multiple groups is tantamount to a rejection and a refusal to examine the claim as drafted, as articulated in *Haas I*, the decision is appealable. Accordingly, Applicants

expressly reserve the right to appeal this decision to the Board of Appeals and/or the federal courts in the event that the restriction requirement is made final.

Second, Applicants respectfully traverse the restriction requirement because the Examiner has not established a *prima facie* case that there is a serious burden upon the Examiner such that the present restriction of the pending claims into the eight Claim Groups is necessary. A serious burden may be *prima facie* established by presenting an appropriate and sufficient explanation of separate classification of the inventions, separate status in the art of the inventions when classifiable together, or a different field of search for one of the distinct subjects. MPEP § 803.01. Furthermore, it is clear that if a search and examination of the entire application can be made without serious burden, the Examiner must examine the application on the merits, even though the application may be deemed to include claims to independent or distinct inventions. MPEP § 803.01. Applicants note that the claims of Groups I, II, III, VI, and VII have been classified in Class 435. The claims of Groups IV and VIII have been classified in both Classes 424 and 435. The claims of Group V have been classified in Class 424. Applicants respectfully submit that the Examiner has not established by sufficient evidence or explanation that it would pose a serious or undue burden to conduct a search and examination of all of the pending claims based upon these classifications. At the very least, Applicants submit that it would not pose a serious burden on the Examiner to search and examine the claims of Groups I, II, III, VI, and VII, since these claims have the same classification. In addition, it would not pose a serious burden on the Examiner to search and examine the claims of Groups IV and VIII, since the claims of these groups have the same classification. Moreover, because the claims of Group V have been classified under both Classes 424 and 435, Applicants respectfully submit that they can be readily searched and examined without serious burden with either the claims of Groups I, II, III, VI, and VII or the claims of Groups IV and VIII.

Third, Applicants respectfully submit the restriction requirement is improper, because it fails to take into account claims 28 and 29. The restriction requirement is thus incomplete.

For at least the foregoing reasons, Applicants respectfully submit that the restriction requirement is improper and request that it be withdrawn. In summary, Applicants have shown that the restriction between Claim Groups I, II, and III is legally improper, because it requires restriction between a number of single claims, and thus the restriction between these groups must be

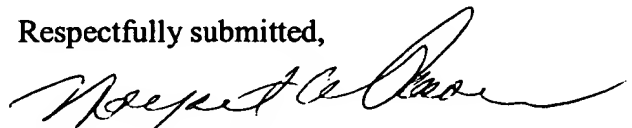
withdrawn. Applicants also respectfully submit that the restriction between at least Groups I, II, III, VI, and VII is improper, because these claims have the same classification and it has not been shown that a search and examination of the claims of these groups would constitute a serious burden on the Examiner. Additionally, Applicants respectfully submit that the restriction between at least Groups IV and VIII is improper, since these claims have the same classification and it has not been shown that a search and examination of the claims of both of these groups would constitute a serious burden on the Examiner. Moreover, Applicants submit the restriction between Group V and at least Groups I, II, III, VI, and VII (classified as Class 435) and the restriction between Group V and at least Groups IV and VIII (classified as Class 424) is improper, because the claims of Group V have been classified under both Classes 424 and 435, and it has not been shown that a search and examination of the claims of these groups would pose a serious burden on the Examiner. Finally, Applicants submit the restriction requirement is improper because it is incomplete, as it fails to take account of claims 28 and 29.

In the event that the requirement is maintained, Applicants provisionally elect Claim Group IV with traverse. Applicants expressly reserve the right to appeal this decision to the Board of Appeals and/or the federal courts in the event the restriction requirement is made final.

Conclusion.

Withdrawal of the restriction requirement and examination of the claims is respectfully requested. If a telephone conference would expedite prosecution of this application, the Examiner is invited to telephone the undersigned at (650) 298-5300.

Respectfully submitted,



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